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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,132	08/18/2003	Robert L. Sullivan	SMI0096.US	3311

7590

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EXAMINER

SHAFFER, RICHARD R

ART UNIT

PAPER NUMBER

3733

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/643,132

Applicant(s)

SULLIVAN ET AL.

Examiner

Richard R. Shaffer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 October 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-12 and 14-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-12 and 14-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4-12, and 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over DiPietropolo (US Patent 4,751,922) in view of Tangram Technology Data File.

DiPietropolo discloses a flexible medullary reamer assembly comprising: a reamer (3) and attachment element both made of metal (**Column 4, Lines 39-41**); a solid or tubular (**Column 3, Lines 32-35** state a bore is optional) flexible shaft having a longitudinal axis and longitudinal length made of thermoplastics or composites (**Claims 2 and 6**), because DiPietropolo required torsional strength, the thermoplastics deemed appropriate would have included those that are rigid, further because the material would be rigid and flexibility required still to feed the shaft through an intramedullary canal, the area moment of inertia would have to be "relatively" low in order to allow for bending; a stainless steel (**Column 4, Lines 57-59**) chuck end (4); and the shaft and reamer to be fixed together (**Column 4, Lines 41-51**).

DiPietropolo discloses all of the claimed limitations except the use of Polyether ether ketone (PEEK) as well as range values for the "low" moment of inertia. Tangram Technology teaches (Introduction, Typical Applications, Physical and Mechanical

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Properties) that PEEK is a "new generation of engineering thermoplastics" that are suitable for use at high temperatures, have excellent chemical resistance, high strength, good resistance to burning, used in prosthetics and instruments, and has a low coefficient of friction and wear rate. DiPietropolo as discussed previously preferred thermoplastics and desired (**Column 3, Lines 29-32 and 55-59**) that the material possess the required degree of flexibility, torsional strength (high strength), resistance to abrasion (low wear rate), and repeatedly called for the ability of being steam sterilized (resistance to burning). It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize PEEK as a thermoplastic in the device of DiPietropolo in order to meet the requirements of wear, torsional strength, heat resistance, and medical use.

In regard to the claimed range values for the "low" moment of inertia falling between 0.0003 inches<sup>3</sup> to 0.000002 inches<sup>3</sup> or 0.0002 inches<sup>3</sup> to 0.00001 inches<sup>3</sup>, it would have been obvious to one having ordinary skill in the art at the time the invention was made to calculate ranges falling within those claimed by using inherent material properties of PEEK to maintain the flexibility found originally in DiPietropolo. It has been held that when the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

***Response to Amendment***

The declaration under 37 CFR 1.132 filed October 9<sup>th</sup>, 2006 is insufficient to overcome the rejection of claims 1, 2, 4-12 and 14-19 based upon DiPietropolo in view of Tangram Technology Data File as set forth in the last Office action because in view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness. The Tangram Technology Data File has countless motivation as to why PEEK would be a desirable material to make an intramedullary reamer to obviate its appropriateness for torque transmission. As described in the previous Office Action, flexibility (for insertion into the intramedullary canal of a longbone) is known to depend upon the design (shape, size) of the structure. Therefore, given the parameters of the problem (the shape of the reamer from DiPietropolo and the desire to use PEEK due to its properties), one having ordinary skill in the art would have calculated the size dimensions and therefore the optimum moments of inertia applicant is claiming. Further, the declaration is not persuasive because the one swearing behind the document is one of the applicants who clearly has a personal interest in the outcome of this patent application.

**Conclusion**

This Office Action is in response to a request for continued examination. All of the claims remain the same with applicant merely continuing to argue the same combination previously set forth. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Richard Shaffer  
October 12<sup>th</sup>, 2006



EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER